



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND
POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

21/DEC/2021

MEMORANDUM

Subject: Name of Pesticide Product: AG36425 R334.1 4 SL Herbicide
EPA Reg. No. /File Symbol: 2749-ANU
DP Barcode: 461018
Decision No: 569356
Action Code: R334.1
PC Code: 103901 (sodium salt of bentazon)

From: Eugenia McAndrew, Biologist *Eugenia McAndrew*
Chemistry, Inerts and Toxicology Assessment Branch
Registration Division (7505P)

To: Endia Blunt, Risk Management Team 23
Herbicide Branch
Registration Division (7505P)

Applicant: Aceto Life Sciences, LLC
c/o Product & Regulatory Associates, LLC

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
Sodium salt of bentazon	44.0
<u>Other Ingredients:</u>	<u>56.0</u>
Total:	100.0%

ACTION REQUESTED: Similarity determination for 2749-ANU, proposed product, and 7969-45, cited product.

BACKGROUND: Aceto Life Sciences, LLC has applied for registration of AG36425 R334.1 4 SL Herbicide, EPA File Symbol 2749-ANU, claiming to be substantially similar to Basagran Herbicide, EPA Reg. No. 7969-45. Both products contain 44% sodium salt of bentazon with the same uses on the labels. The submission includes a proposed Basic CSF and Alternate CSFs #1, #2 and #3 dated December 22, 2020, label, data matrix and company letter.

The registrant is using the selective method of data support to satisfy the acute toxicity data requirements. The data matrix cites acute oral, acute dermal, acute inhalation, primary eye irritation and primary dermal irritation studies with MRIDs 438206-26 to -30 and a dermal sensitization study with MRID 40549009. A search of the OPP electronic file databases shows that the acute oral, acute dermal, acute inhalation, primary eye irritation and primary dermal irritation studies were submitted to support the registration of the cited product, 7969-45. They were reviewed in two Registration Division memos (Blackwell; D222678; EPA Reg. No. 7969-45; 04/JUNE/1996 and Glasgow; D229619; EPA Reg. No. 7969-45; 20/SEPT/1996). No dermal sensitization study was submitted for 7969-45; however, it was classified as a dermal sensitizer based on the Reregistration Eligibility Decision for Bentazon (September 1994). The cited dermal sensitization study (MRID 40549009) in this action was submitted to support the registration of Bentazon Manufacturer's Concentrate, EPA Reg. No. 7969-84, which contains 53% sodium salt of bentazon. The study was reviewed in a 1988 Registration Division memo (Waller; TXR 5012497; EPA File Symbol 7969-IU; 17/NOV/1988). The results of the study were positive for dermal sensitization.

RECOMMENDATIONS:

1. We compared the basic CSFs and labels for the proposed product, 2749-ANU, and the cited product, 7969-45, and determined that the two products are substantially similar.
2. The cited acute toxicity studies with MRIDs 438206-26 to -30 and 40549009 are acceptable to support this registration.
3. The acute toxicity profile for AG36425 R334.1 4 SL Herbicide, EPA File Symbol 2749-ANU, based on the cited data, is as follows:

acute oral toxicity	III	cited	MRID 43820626
acute dermal toxicity	III	cited	MRID 43820627
acute inhalation toxicity	IV	cited	MRID 43820628
primary eye irritation	III	cited	MRID 43820629
primary skin irritation	IV	cited	MRID 43820630
dermal sensitization	positive	cited	MRID 40549009

4. The proposed Basic CSF and Alternate CSF #1, #2 and #3 submitted for 2749-ANU must be reviewed and accepted by the product chemists in the Chemistry, Inerts and Toxicology Assessment Branch.

LABELING: Based on the toxicity profile above, the following are the precautionary and first aid statements for this product:

Product ID #: 2749-ANU

Product Name: AG36425 R334.1 4 SL Herbicide

PRECAUTIONARY STATEMENTS

Signal Word: CAUTION

Hazards to Humans and Domestic Animals:

Harmful if swallowed. Harmful if absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

Personal Protective Equipment (PPE)

Applicators and other handlers must wear:

- Long sleeved shirt and long pants
- Shoes plus socks
- Waterproof gloves

First Aid

If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by a poison control center or doctor.
- Do not give anything by mouth to an unconscious person.

If on skin or clothing:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
- Call a poison control center or doctor for treatment advice

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

User Safety Recommendations:

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
- Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change clothing.